Stepan

Stepan Company

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December 26, 2007

Via Federal Express

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Document Processing Center (Mail Code 7407M)
Room 6428
Attention: 8 (e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1201 Constitution Avenue, NW
Washington, DC 20004

Subject: Notice in accordance with Section 8(e) of TSCA: Results of a range-find study with lauramine oxide (CAS# 1643-20-5).

Dear Sir or Madam:

This letter is to inform you of the results on a range find study (enclosed) with the above referenced substance.

The test was conducted in a static system over 96 hours according to the following test guideline: OECD 201. The following nominal concentrations were tested: negative control, solvent control, 0.0081, 0.027, 0.090, 0.30, and 1.0 mg/l. Under the conditions of this study the calculated 96-hour EC50 value was 0.69 mg/l for cell density and the ErC50 value was greater than 1.0 mg/l for growth rate. At 72 hours, the No Observed Adverse Effect Concentration (NOAEC) for cell density, biomass and growth rate were all 0.090 mg/l. At 96 hours, the most sensitive endpoint tested was biomass. The 96-hour NOAEC for biomass was 0.090 mg/l. While being submitted in accordance with TSCA 8(e), no determination was made as to whether a substantial risk of injury to the health or the environment is actually presented by this finding.

If you have any questions please call Lela Jovanovich at (847) 501-2272.

Sincerely,

8EHQ-08-17028

Lela Jovanovich, Ph.D.
Sr. Research Toxicologist

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Stepan Company conducted a range-find study for and has initiated a Combined Repeated Dose Toxicity Study with a Reproduction/Developmental Toxicity Screening Test (OECD 442 – OPPTS 870.3650) with Lauramine Oxide (CAS # 1643-20-5).

Range-finding Information

In order to set appropriate dosages for the definitive study and to determine the maximum tolerated dose (MTD), a range-finding study was carried out administering the test substance by oral gavage to groups of 3 male and 3 female rats at dosages of 0, 30, 60 and 120 mg/kg/day. Dosages were adjusted using a correction factor of 3.3 to account for purity of the test substance (30.27%) for the purpose of dosage calculation.

The dose levels were selected based on previously conducted toxicity studies in rats: a 2-generation dietary study in which treatment up to and including 40 mg/kg, corrected for purity, caused only a slight reduction of body weight gain in both parent animals and offspring and a developmental toxicity study in which only a slight reduction in body weight gain and food consumption of mothers were noted at 200 mg/kg (not corrected for purity). In this study, mean fetal weight was depressed and was associated with a slight retardation of fetal ossification but parturition, survival and growth and development of F1 offspring were unaffected in females allowed to litter. On this basis the dose levels of 40 a.i. mg/kg and 200 mg/kg (equivalent to 60 mg a.i./kg corrected for purity) seem too low for a dose range finding study since there was no evident toxicity.

At dosages up to and including 120 mg/kg/day (corrected for purity) the only treatment-related observation was that the animals were noted to push their head through the bedding material after administration for almost the whole duration of the study: this was considered a sign of discomfort but not to be an adverse effect. Food consumption, body weight, and body weight gain were not affected by the treatment with the test item. The slight changes noted were considered to be incidental, since there was no dose dependency. In addition, no differences from control animals were noted in the reproductive parameters evaluated at day 14 of presumed pregnancy (mean precoital time, mean number of implantation per dam, pre-implantation losses as a percentage of corpora lutea, and post-implantation losses as percentage of total implantations).

On the basis of these data, it was not possible to establish the dose levels for the main study; therefore two additional dose levels were added to this study in order to test the tolerability at higher doses. The dose levels administered were 1000 and 500 mg/kg in the first and second additional test, respectively, using two male and two female rats per group.

Treatment at the dose of 1000 mg/kg bw (adjusted for purity) caused adverse effects and the death of two animals (a male and a female) after a single administration. The study was terminated for ethical reasons.

At dose level of 500 mg/kg bw (adjusted for purity), adverse effects including piloerection, reduced activity and pushing the head through the bedding material were noted at onset of the treatment. One male rat died after the third administration and the other had diarrhea and hunched posture. The study was terminated for ethical reasons.

Based on the results of this dose range-finding study, dose levels of 40, 100 and 250 mg/kg bw/day were set for the subsequent definitive study.

Definitive Study Information

One female rat in the highest dosage group (250 mg/kg/day, corrected for purity) was found dead on day 6 post coitum, just being noted to push its head through the bedding material after administration, having showed 17 g body weight loss just the day before death and with food consumption data comparable to the other animals of the same group during the pre-paring period. The animal found dead was administered the test substance twenty-two times. At necropsy autolysis had already begun; lungs were incompletely collapsed, the forestomach mucosa appeared irregular and thymus and mandibular nymph node were noted to be dark red.

The in-life part of the main OECD 422/OPPTS 870.3650 study is scheduled to be completed during February 2008; the draft report is expected to be available during March 2008 and final report by April 2008.